

Attorney Docket No.: DEX-0113  
Inventors: Yang et al.  
Serial No.: 10/700,770  
Filing Date: January 16, 2001  
Page 4

#### REMARKS

Claims 1 and 6-8 are pending in the instant application. Claim 8 has been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1, 6 and 7 have been rejected. Claim 1 has been amended. Claims 6 and 7 have been canceled. New claims 9 through 13 have been added. Support for these amendments is provided in the claims as originally filed. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Restriction Requirement

The Examiner has made the following restriction:

Group I, claims 1, 6 and 7 drawn to a method for detecting the presence of lung cancer comprising measuring levels of polynucleotides comprising SEQ ID NO:2-6 from a patient and comparing the levels of the polynucleotides obtained from the patient to controls, classified in class 435, subclasses 5, 6 or class 436, subclass 94; and

Group II, claims 1 and 8, drawn to a method for detecting the presence of lung cancer comprising measuring levels of polypeptides comprising SEQ ID NO: 7-9 from a patient and comparing the levels of the polypeptides obtained from the patient to controls, classified in class 435, subclass 5, 7.1 or class 436, subclass 500.

The Examiner suggests that Groups I and II are unrelated because the methods require measuring two structurally and functionally distinct nucleic acids and used two different components, namely molecules and amino acids.

Attorney Docket No.: DEX-0113  
Inventors: Yang et al.  
Serial No.: 10/700,770  
Filing Date: January 16, 2001  
Page 5

Applicants respectfully traverse this restriction requirement.

MPEP §803 provides two criteria that must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction were not required. Any search of the prior art relating to a specific nucleic acid sequence should reveal any art to the protein encoded thereby. Thus, no serious burden should be placed upon the Examiner by including both Groups I and II in this case.

However, in an earnest effort to advance the prosecution of this case, Applicants confirm their election of Group I, with traverse. Further to facilitate prosecution of this case, Applicants have amended the claims to delete reference to non-elected subject matter. Applicants reserve the right to file a divisional application to the non-elected subject matter.

## **II. Objection to Claim 1**

Claim 1 has been objected to as making reference to nonelected subject matter, namely amino acids. Accordingly, Applicants have amended claim 1 to remove any reference to amino acids. Withdrawal of this objection is therefore respectfully requested.

## **III. Rejection of Claims 1, 6 and 7 under 35 U.S.C. 103(a)**

Claims 1, 6 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bandman et al. The Examiner suggests that Bandman teaches a sequence which is identical to SEQ ID NO:3 and further teaches a method of

Attorney Docket No.: DEX-0113  
Inventors: Yang et al.  
Serial No.: 10/700,770  
Filing Date: January 16, 2001  
Page 6

detecting the polynucleotide of SEQ ID NO:3 for the purposes of detecting or diagnosing cancer. The Examiner has acknowledged that Bandman do not specifically teach that the levels of the polynucleotide have to be at least two times higher than the control sample. However, the Examiner suggests that this is an obvious variation of the reference teaching absent a showing of unobvious property. The Examiner cited *In re Aller* as holding that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Applicants respectfully traverse the rejection.

At the outset, it is respectfully pointed out that claim 1 has been amended to be drawn only to SEQ ID NO:3. Claims 6 and 7 have been canceled in light of this amendment and new claims 9 through 13, drawn to other sequences set forth originally in claim 1 have been added. Thus, this rejection only pertains to amended claim 1.

Further, Applicants respectfully disagree with the Examiner's characterization of Applicants' discovery, that levels of SEQ ID NO:3 at least two times higher than the control sample are diagnostic for lung cancer, as an obvious variation and optimization of the teachings of Bandman. MPEP § 2144.05 part II A refers to optimization of variables, e.g. conditions or proportions. The phrase "at least two times higher" within claim 1 does not refer to an optimized condition, but instead is a property of the instant invention not obvious by the disclosure of Bandman nor obvious to one of skill in the art at the time of filing. Bandman fails to meet or render obvious the physical property that a nucleic acid of the present invention is

Attorney Docket No.: DEX-0113  
Inventors: Yang et al.  
Serial No.: 10/700,770  
Filing Date: January 16, 2001  
Page 7

expressed at least two times higher in lung cancer than in normal controls.

Additionally, Bandman does not recognize that a molecule expressed "at least two times higher" in one sample as compared to a control is a result effective property. It is well known in the art that the smaller the difference in expression between samples, the more difficult it is to accurately determine the significance of the differential expression, e.g. a molecule with minimal differential expression between disease and control samples may not accurately identify diseased patients.

Therefore, the term "expressed at least two times higher" is a property of the instant invention related to the efficacy of the molecule to readily detect the presence of lung cancer compared to a control which Bandman does not disclose or render obvious.

MPEP 2143 is clear; to render an invention obvious the cited prior art must teach or suggest all of the claim limitations.

Since Bandman neither teaches nor suggests the limitation in the instant claims that SEQ ID NO:3 is expressed at least two times higher in lung cancer as compared to normal controls, this reference cannot render obvious claim 1.

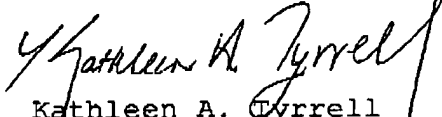
Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

Attorney Docket No.: DEX-0113  
Inventors: Yang et al.  
Serial No.: 10/700,770  
Filing Date: January 16, 2001  
Page 8

#### IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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